

Award Number:
W81XWH-08-2-0045

TITLE:
Military to Civilian: RCT of an Intervention to Promote Postdeployment Reintegration

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REPORT DATE:
October 2010

TYPE OF REPORT:
Annual

PREPARED FOR:
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188		
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1. REPORT DATE (DD-MM-YYYY) 01-10-2010		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 2 SEP 2009-1 SEP 2010	
4. TITLE AND SUBTITLE Military to Civilian: RCT of an Intervention to Promote Postdeployment Reintegration			5a. CONTRACT NUMBER		
			5b. GRANT NUMBER W81XWH-08-2-0045		
			5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S) Sayer, Nina, A., PhD (Principal Investigator); Orazem, Robert, J., MA (Project Coordinator)			5d. PROJECT NUMBER		
			5e. TASK NUMBER		
			5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Minnesota Veterans Research Institute Minneapolis, MN 55417			8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)		
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)		
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study seeks to determine whether Internet-Based Expressive Writing (IB-EW), a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms and improve functioning among veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations, its efficacy in combat veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also attempt to identify individual difference characteristics related to the efficacy of the treatment, to indicate who is most likely to benefit from the treatment in order to inform treatment implementation strategies.					
15. SUBJECT TERMS Research Study, Randomized Controlled Trial, Expressive Writing, Internet-based Intervention, OEF/OIF Veterans, Post-deployment Reintegration					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 13	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION:

This study seeks to determine whether Internet-Based Expressive Writing (IB-EW)¹, a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms² and improve functioning³⁻⁵ among veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations⁶, its efficacy in combat veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also attempt to identify individual difference characteristics related to the efficacy of the treatment, to indicate who is most likely to benefit from the treatment in order to inform treatment implementation strategies.

BODY:

This section of the Annual Report is organized according to the study's Statement of Work (SOW) for Years 1 and 2, which appear throughout this section in underlined font.

Milestone 1: Preparing for Implementation (Month 1-12)

We continued to address remaining tasks for Milestone 1 during Year 2.

Task 1: Obtain required approvals (Months 1-9)

- **VA and DoD IRB & R&D approvals (Month 1-6)**

Appropriate human subjects protection approvals were obtained in Year 1. In Year 2, we obtained IRB approvals for a number of protocol amendments. We obtained VA IRB continuing review approval in May 2010. We submitted HRPO continuing review materials in July 2010; as of the end of the current reporting period, these materials remained under review.

- **VA Central Office approval to obtain real SSNs and address information (Month 6-9)**

Completed in Year 1.

- **VA Central Office approval to access OIF/OEF Roster (Month 6-9)**

Approvals to obtain OEF/OIF roster pulls from VA's VHA Support Service Center (VSSC) for VA users and from DoD's Defense Manpower Data Center (DMDC) for VA non-users were obtained in Year 1. During Year 2, we were referred by DMDC to VA's Environmental Epidemiology Services (EES) office to obtain the DoD OEF/OIF roster. We gained approval from EES to do so and learned that we would be able to obtain both VA users and non-users from this one source. We cancelled our data use agreement for OEF/OIF with VSSC for quarterly roster pulls in March 2010. In the future we will obtain all roster pulls from EES.

- **OMB Exemption for Research (Month 6)**

Completed in Year 1.

- **Web Ops review of project web application and posting of application on the VA Web Ops server (Month 6-9).**

During Year 1, after pursuing a number of routes to implement our study website on the internet, we obtained approval from the office of VHA Web Communications in March 2009

to launch the study website on VA servers. We were then allowed to post our study website to VA Web Ops web development server space (VA intranet) while the website underwent a lengthy Certification and Accreditation (C&A) review process designed to ensure the performance, security, and integrity of VA web applications before they are allowed to launch on web production servers (the internet).

We completed the C&A process during Year 2. We obtained approval for our website's minor application review packet, including thorough review of the application's and the study team's privacy and security features, plans, and procedures. As well, the application was submitted to a series of application scans ("app scans") that evaluate the application's underlying programming code for potential security or performance vulnerabilities as well as the application's adherence to Federal and VA policies and regulations for templating, accessibility, and content. During this process, the website was reprogrammed to accommodate app scan feedback, changes in VA's website template requirements that were released in November 2009, and a position reversal by VA IRB in October 2010 rescinding their prior approval for the study to use email communications that necessitated significant changes to the study's recruitment and enrollment procedures and consequently to the study's web application. Live internal pilot testing of the resulting web application yielded additional revisions. A final version of the website for pilot recruitment was developed and final app scan approval was obtained. Following app scan and minor application review packet approval, the study's application was referred to VA's Austin Information Technology Center for final authority to operate in May 2010.

The study's website was promoted by VA Web Ops to the internet in June 2010. However, we were unable to begin using it because VA Web Ops had not secured it with secure socket layering (SSL) which is required due to collection of sensitive data. SSL protection was added in August 2010, and the study team conducted further internal pilot testing to evaluate the applications' performance on the internet, for example given the wider variety of web browser applications and security preferences and settings extant outside the VA intranet system. A final pilot version of the website was posted to the internet in August 2010, at which point pilot recruitment began.

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

We proposed to create a sample of 800 participants for piloting, randomly pulled from the OEF/OIF veteran roster population and stratified by VA user status (user, non-user), gender (male, female), and race (white, nonwhite, unknown). We obtained a stratified sample of 400 VA users in a roster pull from VSSC in September 2009 and obtained address information for these individuals from VA's National Patient Care Database in November 2009. We then obtained a stratified sample of 385 VA non-users for piloting from VA's EES, including participants' addresses, in December 2009. (A small number of these VA non-users were eliminated from this roster pull because they appeared in the VSSC roster of VA users). The VSSC and EES roster pulls were then combined to create a final pilot recruitment sample of 785 individuals.

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Completed in Year 1.

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

Following promotion of the study's website to the internet, the addition of SSL security protection, and final internal testing of the website on the internet, a final pilot version of

the website was posted to the internet and pilot recruitment was initiated in August 2010. Pilot participant enrollment began after the current reporting period, in September 2010.

Milestone 2: Data Collection (Month 13-36)

We initiated pilot participant recruitment at the end of Year 2, in August 2010. We will continue to pilot the website and study procedures for three months. The study's main recruitment, including Tasks 5-13 below, is expected to commence in approximately November 2010.

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month follow up assessment online (Month 22-36).

Task 13: Contact of participants who fail to complete 3-month and/or 9-month follow up assessments as scheduled (Month 16-36).

KEY RESEARCH ACCOMPLISHMENTS:

Veteran Rosters

1. We obtained our first quarterly OEF/OIF roster pull of all OEF/OIF VA users from VSSC in September 2009.
2. We employed the study's randomization with stratification sampling plan for pilot recruitment to select a sample of 400 VA users from the VSSC roster to construct half of our pilot recruitment sample.
3. We received approval from DMDC to obtain DoD's OEF/OIF roster, which includes both VA users and non-users, and were referred to VA's Environmental Epidemiology Service to implement DMDC roster pulls.
4. We contacted EES to set up our first DoD roster pull and submitted all paperwork they required for roster pull approval. We learned that due to the specifics of their data use agreement with DoD, EES could not release the entire roster to us; rather they would need to create our sample pulls for us.
5. We submitted the study's sampling plan for pilot recruitment to EES and received a roster pull of VA non-users for piloting. However, a number of cases in that sample were also present in the roster of VA users we previously obtained from VSSC and were therefore excluded, leaving a total of 385 VA non-users for piloting.
6. We combined the 385 VA non-users obtained from EES with the 400 VA users obtained from VSSC to create our final pilot recruitment sample (n = 785).
7. To prepare for pilot recruitment, we obtained address information for all individuals in the pilot sample. EES included address information in the roster pull they performed for us for VA non-users. For the VA users obtained from VSSC, we obtained address information via an approved request submitted to VA's National Patient Care Database.

8. We communicated with EES and VSSC regarding the discrepancy between the two data sources in VA user status for some individuals but were unable to determine the exact source of the discrepancies. As a result, we made arrangements to obtain all future roster pulls from one source, VA's EES, to ensure consistent methods for identifying potential participants.
9. We put our quarterly roster request from EES on hold because we have a sufficient sample of participants identified for piloting and will not need additional cases pulled until the study's main recruitment. We made plans with EES for resuming roster pulls for the study's main recruitment when needed.

Human Subjects Protection/IRB

10. We submitted a number of protocol amendments to IRB for review in preparation for study implementation. All amendments were approved with one exception; an amendment documenting the specific content of previously-approved procedures for communicating with study participants (e.g., sending automated emails reminding participants of upcoming or missed sessions) was tabled in October 2009 due to concerns about using email to communicate with participants.
11. Subsequent to the above (#10), we pursued approval to use email communication with participants as originally proposed, meeting with IRB and working with local privacy and information security personnel. Concurrently, we developed a set of alternate procedures for communicating with study participants that did not include the use of email (e.g., using phone calls and US mail for upcoming or missed session reminders). These alternate procedures were approved by IRB in December 2009 and incorporated into the study procedures and website programming.
12. We continued to pursue approval to use email communications as originally planned. After our facility privacy officer indicated that he would not consider allowing the use of email without top-down guidance, we focused our efforts on working with regional and national personnel to gain authorization to use email communications, and were ultimately able to gain and document the support of the deputy director of VHA Web Communications. We then secured the support of our facility privacy officer and were advised to resubmit our plan to use email communications to IRB.
13. We submitted a revised plan for using email communications to IRB and gained approval in March 2010; we retained some of the revised procedures because they had been incorporated into the website's programming, to avoid further delays in the website's review process.
14. Our original IRB-approved protocol included a safety plan designed to ensure that distressed participants have access to assistance 24 hours a day, that participants requesting assistance receive prompt response and follow-up from appropriate mental health providers, and that the study team responds appropriately to indications of risk that may appear in participants' online writing submissions regardless of whether those participants request assistance. During the current reporting period, we refined the study's safety plan, for example in response to changes in the communication strategies for which we have IRB approval and based on our increased knowledge of the technical capabilities of the study website and related systems and infrastructure (e.g., the migration of data from VA Web Ops servers to local servers accessible by study personnel).
15. As part of our study's safety plan, we previously identified an individual to serve as the study's risk assessor – a licensed mental health clinician outside the study team to assist in participant risk assessment and intervention as necessary. That individual is no longer able to serve in this role and we identified a new individual to serve as our Risk Assessor and added him to our IRB protocol. The study's current Risk Assessor, Dr. Kyle Curry, was consulted in the development of the revised safety plan.

16. We submitted the final revised safety plan to IRB and gained approval in August 2010. We then distributed copies to appropriate personnel (e.g., the study's risk assessor and medical monitor) prior to study implementation.
17. We submitted materials to our facility's IRB in March 2010 for annual continuing review; approval was granted in May 2010.
18. We submitted materials to DoD's HRPO in July 2010 for annual continuing review. These materials were under review at the end of the current reporting period.

Internet Application

19. During a previous reporting period, our request for a VA website was approved and we were granted web development space on VA's internal servers (the intranet). We then initiated the VA Web Ops Certification and Accreditation (C&A) process for the website, which entails submission of a minor application review packet and "app scans" of the website's programming code, and continued to work through that process during the current reporting period.
 - a. During the current reporting period, we submitted a minor application review packet for the study's website in consultation with our facility ISO, facility privacy officer, and Web Ops personnel. We continued working with Web Ops throughout the review, for example making required changes to submitted documents and resubmitting a number of the required documents after their required templates were changed.
 - b. During the current reporting period, we submitted the study's website to a series of application scans ("app scans") that evaluate the application's underlying programming code for potential security or performance vulnerabilities as well as the application's adherence to Federal and VA policies and regulations. During this process, the website was reprogrammed to accommodate app scan feedback, changes in VA's website template requirements that were released in November 2009, a position reversal by VA IRB in October 2010 rescinding their prior approval for the study to use email communications, feedback from a review of the website's compliance with accessibility requirements as stipulated by Section 508 of the Federal Rehabilitation Act, and a final round of live internal pilot testing. The website was then finalized and submitted for final app scan approval.
 - c. Following app scan and minor application review packet approvals, the study's application was referred to VA's AITC for final authority to operate and then promoted from web development servers (the intranet) to VA's web production servers (the internet) in June 2010.
20. When the study's website was promoted by VA Web Ops to the internet in June 2010, we discovered that it had not been secured by VA Web Ops with secure socket layering (SSL), which we had been informed was necessary due to the website's collection of sensitive data. VA Web Ops submitted a request for SSL protection to VA's Enterprise Security Change Control Board (ESCCB), which was approved in August 2010; SSL protection was then successfully added to the website.
21. Prior to initiating pilot testing with the study's pilot participants, the study team conducted a round of internal pilot testing to evaluate the applications' performance on the internet, for example given the wider variety of web browser applications and security preferences and settings that exist outside the VA intranet system.
22. During internal piloting, it became apparent that some web browsers cannot recognize VA servers' security certificates and that, consequently, the website's SSL protection causes those browsers to warn users that they are attempting to enter an unsecure website. We attempted to resolve this issue, which could potentially adversely affect recruitment rates, with VA Web Ops, but learned that it is a system-wide issue that it is

not presently fixable. We therefore gained IRB approval to add an informational handout to our recruitment packets to facilitate pilot participants successfully navigating to the study's website.

23. Following a number of minor revisions to the website resulting from our internal pilot testing, a final pilot version of the website was posted to the internet in August 2010.

Piloting

24. We have IRB approval to contact up to $n = 800$ and enroll up to $n = 300$ pilot participants. During the current reporting period, we obtained roster pulls from two data sources and constructed a pilot recruitment sample of $n = 785$.
25. During the current reporting period, the study team identified a plan for sending recruitment materials to pilot participants in approximately-weekly mailing waves; pilot participants will be contacted for recruitment in 9 sets of mailings sent out across 11 weeks.
26. We assigned each individual in the pilot recruitment sample to a mailing wave using randomization with stratification (gender by race by VA user status) to ensure balanced numbers of participants from each recruitment strata across the 3-month piloting window.
27. Our first wave of recruitment mailings was sent out in late August 2010 after a final, secure version of the study website was posted to the internet.
28. No pilot participants enrolled during the current reporting period; pilot recruitment began at the end of the reporting period, in late August. Pilot participant enrollment then began after the current reporting period, in September 2010. We plan to continue piloting for approximately three months.

Administrative

29. We met regularly as a project team to coordinate project activities.
30. We updated the study's entry in the U.S. National Institutes of Health's clinicaltrials.gov website.
31. We submitted quarterly technical progress reports to DoD's U.S. Army Medical Research and Materiel Command.
32. We maintained a critical documents binder for the study, including both a paper version and an electronic backup copy of each document.
33. A research assistant for the study was hired in October 2009, oriented to the project, added to the IRB protocol, and trained.
34. Study personnel attended professional development trainings and participated in online webinars on topics relevant to the study, for example detecting suicide risk among DoD and veteran populations, social media use among OEF/OIF veterans, and information VA researchers should know about VA's electronic health record system.
35. We updated the instruction set for the experimental intervention based on feedback from the intervention's developer (who is also a co-investigator on the study).
36. We made a number of minor revisions to the study's questionnaires, for example updating questions about participants' use of information technology.
37. We developed and refined a software program to internally track study participants over the course of their involvement in this longitudinal study. This tracking application is used for managing recruitment mailings, session reminders, and other study procedures. A tracking application that is separate from the online study application is necessary because we cannot store personally-identifiable information on Web Ops servers that house the study's internet application. The tracking application instead resides on secure local servers behind the VA firewall and is accessible only to key study personnel.

38. We obtained LIWC text-scanning software and gained approval from our facility information security officer to install this software on our network. We plan to use this software to scan participant writing samples for keywords that may confer elevated risk (e.g., “suicide”) during data collection and to construct important intervention-related process variables for secondary analysis. Once installed, study staff familiarized themselves with the software and, in particular, evaluated its utility for risk detection.
39. The study team purchased Atlas.ti qualitative analytic software, installed it on study workstations, and completed a training workshop on its use. This software will be used for qualitative data analysis of participant writing samples.
40. We ordered, obtained, and compiled study materials, including recruitment materials (e.g., envelopes, return envelopes, promotional magnets to help participants remember the study’s web address, etc.), participant tracking materials (e.g., session reminder postcards, contact information update forms, etc.), and other study materials (e.g., study brochures, business cards, etc.) during the current reporting period. We also secured storage space in our facility for these materials and started compiling recruitment packets in anticipation of piloting.
41. Participant incentives for this internet-based study will be provided in the form of electronic Amazon.com gift card codes. We established an Amazon.com “corporate account” to enable bulk purchasing of these gift card codes and ordered a sufficient quantity for piloting. We received an encrypted file containing these gift card codes during the current reporting period and loaded them into the study’s web application.
42. We obtained new telephone equipment for select study staff to allow for call transfers and revised the configuration of the study’s toll free phone number to facilitate our responses to participant phone calls.
43. The study team held a pre-implementation meeting in June 2010 to prepare for piloting.
44. The study team met with key stakeholders to establish working relationships, gain expert feedback about OEF/OIF programming, and educate them about the project, including our facility’s OEF/OIF program team and clinical provider groups (e.g., the posttraumatic stress treatment program, mental health intake team, after hours psychiatric emergency personnel).
45. We established a contract with the University of Minnesota Health Survey Research Center (HSRC) for assistance with identifying contact information for recruitment and tracking participant contact information over the course of their participation in the study. We arranged for HSRC personnel to come to our VA facility to gain authorization to access VA servers to perform their work for this study. Once pilot recruitment began, we referred individuals whose mailing address was no longer valid to HSRC for new address tracking and worked with HSRC to problem solve difficulties accessing VA servers that arose during piloting.
46. We met with the study’s DoD portfolio manager by conference call in August 2010 to discuss the study’s timeline.
47. No participants were enrolled as of the end of the current reporting period. Pilot participant enrollment began after the current reporting period, in September 2010, and we anticipate the study’s main recruitment to begin in approximately November 2010.

REPORTABLE OUTCOMES:
(None)

CONCLUSION:

In Year 2 we continued to devote our efforts to gaining approvals necessary to implement the study protocol, most notably approval to post the study’s website to the internet. This

study includes an implementation approach – using the internet to deliver an intervention to participants in the context of a clinical trial – that is novel within the VA research system, and we have met significant administrative challenges. We received approval to have a VA website through which to implement our study in March 2009 and worked continuously throughout Year 2 on gaining VA Web Ops’ approval to actually post the website to the internet; this was ultimately achieved in August 2010, 17 months after our request for a VA website was initially approved. Throughout that process, we continued working toward preparing all other aspects of the study for implementation, for example compiling a sample of pilot participants and gaining their contact information for recruitment. When our website was made available online we immediately began pilot recruitment, at the very end of this reporting period. Pilot participant enrollment began in the first month of the following reporting period. We are aware of our study’s timeline demands and are sensitive to the need to adhere to the study’s Milestones as faithfully as possible. During pilot recruitment, one of our planned tasks is to identify the workload burden of different recruitment rates to ensure that we are able to implement the study’s main recruitment at a higher rate than previously proposed, to shorten the overall duration of the main recruitment period. Included in the study’s Milestones are dissemination activities in the final year of the study, to include disseminating scientific findings through manuscript publication activities as well as disseminating administrative and process feedback (“lessons learned”) to relevant VA and DoD stakeholders. As part of the latter, we anticipate providing feedback to stakeholders regarding the barriers to implementation that we have experienced and the need for streamlining a number of relevant administrative processes (most notably, the process for applying for VA web development space for research).

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APPENDIX A: Statement of Work (SOW)

Milestone 1: Preparing for Implementation (Month 1-12)

Task 1: Obtain required approvals (Months 1-9)

- VA and DoD IRB & R&D approvals (Month 1-6)
- VA Central Office approval to obtain real SSNs and address information (Month 6-9)
- VA Central Office approval to access OIF/OEF Roster (Month 6-9)
- OMB Exemption for Research (Month 6)
- WebOps review of project web application and posting of application on the VA WebOps server (Month 6-9).

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

Milestone 2: Data Collection (Month 13-36)

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month follow up assessment online (Month 22-36).

Task 13: Contact of participants who fail to complete 3-month and/or 9-month follow up assessments as scheduled (Month 16-36).

Milestone 3: Data Preparation (Month 37-39)

Task 14: Clean and merge assessments for data analysis (Month 37-38).

Task 15: Upload participant's essays into ATLAS.ti for coding (Month 37-40)

Task 16: Extract VA service use data for all participants from VA administrative databases; clean and merge data (Month 39)

Product: Data sets ready for analysis

Milestone 4: Data Analysis, Dissemination and Products (Month 40-48)

Task 17: Conduct statistical analyses to address primary hypotheses (Month 40-42)

Product: Tested web-based intervention for improving outcomes among OIF/OEF veterans with post-deployment reintegration problems that can be used throughout VA for very little expense.

Task 18: Code participant essays (Month 40-43)

Task 19: Analyze coded essays (Month 43-45)

Product: Catalogue of post-deployment reintegration challenges and needs from the perspective of OIF/OEF veterans that can be used to inform other interventions

Task 20: Dissemination and implementation plan meeting in Minneapolis (Month 43)

Task 21: Conduct statistical analyses to address secondary and exploratory hypotheses

(Month 43-45)

Task 22: Dissemination Activities/Products and Deliverables (Month 46-48)

- Manuscript preparation (Product)
- Report writing (Product)
- Executive summary preparation and distribution to DoD and VA stakeholders (Product)
- Presentations to DoD and VA stakeholders (Product)
- Presentations at scientific meetings (Product)